

Appln No.: 09/944,326
Amendment Dated: June 17, 2004
Reply to Office Action of February 17, 2004

REMARKS/ARGUMENTS

This is in response to the Office Action mailed February 17, 2004 for the above-captioned application. Reconsideration and further examination are respectfully requested

An extension of time sufficient to make this paper timely is requested and the fee is enclosed. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

Claims 6-11 and 20 have been canceled. As a result, claims 1-5, 12-19 and 21-27 remain in this application. As a result of an election of Seq. ID No. 4, claims specifically directed to Seq. ID No. 5 and 12 are withdrawn from consideration. Claims 1, 2 12-15 and 22-27 are generic.

The Examiner provisionally rejected claims 1-3, 6-9, 12-16 and 22-27 for obviousness-type double patenting in view of claims 1 of copending application serial no, 10/080,794. Applicants respectfully traverse this rejection.

The present application has a filing date prior to the filing date of the cited application. Thus, as set forth in MPEP section 804, a two-way test for obviousness of the claims must be considered. This means that one must consider both whether the claims of this application would be obvious over the cited application, and whether the cited claims of the base application are obvious over the claims of this application. The Examiner does not appear to have applied such a two-way test. When this test is performed, however, it is apparent that the obviousness-type double patenting rejection is in error.

The claims of the present application relate to antisense compositions, and in some cases include specified sequences. Claim 1 of the cited '794 application recites a single oligonucleotide sequence, and identifies specific sites of backbone modification for this sequence. Thus, the claims of this application are generic with respect to the species claimed in the '794 application. It cannot fairly be said, however, that the specific composition claimed in the '794 application is obvious over the generic claims of this application. The specific sites of modification are not suggested by the mere existence of the genus, nor of the nucleotide sequence accompanied by a disclosure that this may be modified to enhance stability (for example as in claim 15 of the present application). For this reason, the two-way test is failed, and the provisional rejection should be withdrawn.

The application has been amended so that the remaining claims all refer to a pharmaceutical composition that contains both an antisense oligonucleotide, and "a pharmaceutically acceptable carrier suitable for human administration for providing the

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oligonucleotide to a mammalian subject to reduce expression of TRPM-2." Support for the amendment to claim 1 is found, *inter alia* in claim 22 as filed.

The Examiner rejected claims 1, 2, 6, 7, 8, 22, 23 and 27 as anticipated under 35 USC § 102(b) by Sensibar. In formulating this rejection, the Examiner did not indicate where in the Sensibar disclosure there is a teaching of a pharmaceutical carrier suitable for human administration even though this limitation was found in three of the claims rejected as anticipated. Sensibar teaches the use of Lipofectin™ as a carrier. Lipofectin, and DOTMA which is the cationic lipid in Lipofectin®, however, is known to be unsuitable for *in vivo* use in humans, even though it may be useful to some extent in *in vitro* processes. See, for example, US Patent No. 6,020,317, Col. 2, lines 19-23. Thus, Sensibar does not anticipate any of the claims as now pending.

Furthermore, Sensibar does not render the claims obvious. Sensibar does not disclose or suggest any therapeutic utility for the antisense compounds disclosed therein as research tools into the mechanism of TNF- α induced cell death. There would therefore be no motivation to make the compositions of the invention.

For the foregoing reasons, Applicants submit that all of the pending claims are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully Submitted,



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